Remarks

Amendments to the Claims

Applicants have made several amendments to independent claim 1 in an effort to advance prosecution. First, amended claim 1 incorporates the limitations of claim 3 and now recites several particular types of cancer. Second, amended claim 1 now recites "human" instead of "mammal." Third, amended claim 1 is directed to a screening method, rather than a method for diagnosing. The amendments are supported on page 67, lines 17-25, and by Example 1.

Claim 1 also is amended to recite "detectable" amplification. This amendment is supported, *inter alia*, by the specification's disclosure of various methods of measuring gene amplification including, for example, Southern blotting, *in situ* hybridization, comparative genomic hybridization (CGH), amplification-based assays (*e.g.*, a PCR-based TaqMan assay), and DNA microarray-based CGH (page 73, line 17 to page 76, line 5). Each technique used to measure gene copy number has an inherent detection limit, and the detection limit will be different for each technique (indeed, even for the same technique employing, for example, different instrumentation).

New claims 135-138 are supported by Table 2 on page 113.

Rejection Under 35 U.S.C. § 102(b)

The Final Office Action maintains the rejection of claims 1-3 under 35 U.S.C. § 102(b) over Suehiro.[1] Claim 3 has been canceled. Applicants respectfully traverse the rejection of claims 1 and 2.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Independent claim 1 recites "determining SPHK1 gene copy number . . . . thereby generating data for a test gene copy number" and "comparing the test gene copy number to data for a control gene copy number . . . ."

The Examiner contends that Suehiro's disclosure of amplification of the genetic region 17q25-ter and its apparent association with ovarian cancer is the same as a disclosure of amplification of the SPHK1 gene's association with this disease. Paragraph bridging pages 17 and 18 of the Office Action. This is not the case. Many genes are contained within the 17q25-ter region, and Suehiro does not mention the SPHK1 gene at all. In effect, the Examiner argues that disclosure of a genus (amplification of genes in the 17q25-ter region) anticipates a species (amplification of SPHK1). This is not the law. See *In re Meyer*, 599 F.2d 1026, 1031, 202 U.S.P.Q. 175, 179 (C.C.P.A. 1979) ("The genus, 'alkaline chlorine or bromine solution,' does not identically disclose or describe, within the meaning of § 102, the species alkali metal hypochlorite, since the genus would include an untold number of species.").

Suehiro does not expressly or inherently teach determining SPHK1 gene copy number or that amplification of an SPHK1 gene in a test sample relative to a control indicates the presence

[1] Suehiro *et al.*, "Genetic Aberrations Detected by Comparative Genomic Hybridization in Ovarian Clear Cell Adenocarcinomas," *Oncology 59*, 50-56, 2000.

of a precancerous lesion or a cancer in a mammal. Suehiro therefore does not anticipate claims 1 or 2. This argument applies with equal force to new claims 135-138.

Please withdraw the rejection.

Rejections Under 35 U.S.C. § 112 ¶ 1

Claims 1-3 stand rejected under 35 U.S.C. § 112 ¶ 1 as neither described nor enabled. Applicants respectfully traverse the rejections.

Claim 3 has been canceled. Applicants believe the amendments to claim 1 moot the Examiner's bases for rejecting claims 1 and 2.

Please withdraw the rejections.

Respectfully submitted,

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